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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,669	01/24/2002	Ibert C. Wells	N1427-005	1066

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT PAPER NUMBER

1644

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,669

Applicant(s)

WELLS, IBERT C.

Examiner

Michael Szperka

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 and 21-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/19/03, 2/24/03, 6/6/03 and 8/8/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group I, peptide species SEQ ID NO: 2 in the reply filed on August 12, 2004 is acknowledged. The traversal is on the grounds that the restriction between Group I and Groups II/III is not proper as they are not related as product and process of use, that there is no serious additional burden in searching the methods of Groups II and III together, and that there is no additional search burden concerning the polypeptide sequences recited in the claims.

This is not found persuasive because Groups I and II/III are properly related as product and process of use. The examiner agrees with Applicant that the antibody of Group I can be used for western blotting, and that western blotting can be used as a method of detecting (Group II) or monitoring (Group III). However, the antibody has other uses not directed toward detecting or monitoring, such as in the purification of tachykinins or in therapeutic treatments in which the antibody is administered to patients suffering from a physiological disorder characterized by an excess of tachykinin peptides. Therefore, the restriction requirement between Groups I and II/III is maintained.

Upon further consideration, the examiner agrees with Applicant that the method steps of Groups II and III are substantially similar and that art that anticipates or renders obvious the claims of one group would also apply to the

Art Unit: 1644

other group. Therefore, the restriction requirement between Groups II and III is withdrawn.

An antibody that specifically binds a peptide consisting of SEQ ID NO: 2 appears to be free of the prior art, and as such the prior art search has been extended to other peptide species.

The restriction requirement between the product and process of use is still deemed proper and is therefore made FINAL.

Claims 1-8, 11-12, and 21-22 have been amended.

Claims 18-20 have been canceled.

Claims 24-28 have been added.

Claims 1-17 and 21-28 are currently pending in this application.

Claims 11-17 and 21-27 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 1-10 and 28, drawn to an antibody, or a diagnostic reagent that comprises said antibody, that specifically binds a tachykinin peptide are under consideration in the instant application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 2, 7-10 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody that specifically binds the sequence of SEQ ID NO: 1 and SEQ ID NO: 4 does not reasonably provide enablement for an antibody that specifically binds SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant has claimed an antibody that binds an amino acid sequence found in the C terminus of all mammalian tachykinins, FXGLM, where X is either F or V (SEQ ID NO: 4). FFGLM (SEQ ID NO: 1 and one of the possibilities of SEQ ID NO: 4) and FGLM (SEQ ID NO: 2) are found in substance P (SP), while FVGLM (the other possibility for SEQ ID NO: 4) is found in neurokinin A (NKA) and neurokinin B (NKB). One of the properties recited for this antibody in claims 9 and 10 is that it is cross-reactive with SEQ ID NO: 1, 2, and 4. Applicant has also disclosed general guidelines that are well known in the art for how to produce both polyclonal and monoclonal antibodies (paragraphs 26 to 46 of the instant specification), but it is not disclosed that Applicant generated antibodies that had the desired specificity.

Couraud et al. (J. Neurochemistry, 1987, 49:1708-1718) disclose the production and characterization of monoclonal antibodies and a polyclonal serum that bind SP using standard techniques (see entire document, particularly the Materials and Methods section, pages 1709-1711). Table 3 (page 1714) details

Art Unit: 1644

the percent relative binding of the polyclonal antiserum and five monoclonals for SP, SP analogues substituted with alanine, fragments of SP, and other tachykinins. All of the monoclonal antibodies and the polyclonal sera specifically recognize SP, a fragment of SP that corresponds to SEQ ID NO: 1 (listed as SP (7-11)), and neurokinins A and B. None of these antibodies demonstrate any reactivity toward the SP fragment that corresponds to SEQ ID NO: 2 (SP (8-11)). Couraud et al. state that position 7 appears to be the most crucial for recognition since neither the SP (8-11) truncation nor the peptide where position 7 is changed to alanine are specifically bound by any of the antibodies (Fine specificities of anti-SP mAbs, starting on page 1712, end of the right column and continuing to page 1714, particularly page 1713, middle of the left column, sentence starting "However, it is..."). Couraud et al. also note that the polyclonal sera shows a pattern of specificity similar to the monoclonal antibodies, indicating that the serum did not contain antibodies with markedly different specificities (page 1713, right column, end of the paragraph that started on page 1712).

Based upon the teachings of Couraud et al., it does not appear that an antibody that specifically binds a sequence consisting of SEQ ID NO: 2 can be made using standard art recognized techniques, but antibodies that specifically bind a sequence consisting of SEQ ID NO: 1 or 4 can be successfully produced. Applicant has not disclosed that an antibody that specifically binds a sequence consisting of SEQ ID NO: 2 has been made, nor has Applicant indicated any additional techniques in addition to those commonly known in the art that would be required to overcome the difficulty in generating an antibody that specifically

Art Unit: 1644

binds a sequence consisting of SEQ ID NO: 2. The scope of the claims must bear a reasonable correlation with the scope of enablement set forth. Without additional guidance, it is not possible to practice the full breadth of Applicant's claims as an undue amount of experimentation would be required to make an antibody that specifically binds a sequence consisting of SEQ ID NO: 2, and this experimentation left to those of skill in the art is unnecessary, improper, extensive and undue.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 and 28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

These claims are directed an antibody that binds a sequence found in the C terminal amino acid residues of the mammalian tachykinins substance P, neurokinin A and neurokinin B. These peptides occur in nature and it is possible that an antibody with the desired specificity could be found in a pre-immunized animal, thus making the antibody a product of nature. It is suggested that Applicant amend the claim to, for example, "An isolated and purified antibody ..." to overcome this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6, 9-10, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Couraud et al. (J. Neurochemistry, 1987, 49:1708-1718, see entire document).

Couraud et al. teach the generation of a polyclonal serum and five monoclonal antibodies that specifically bind sequences consisting of SEQ ID NO: 1 and 4 (see Table 3 on page 1714 and discussion of this reference supra) and that these antibodies can be used as diagnostic reagents in immunocytochemistry (page 1714, left column starting Use of mAbs in immunocytochemistry), EIA and RIA applications (page 1717, left column, the second to the sixth full paragraph). Therefore, the prior art anticipates the claimed invention.

7. No claims are allowable.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

Art Unit: 1644

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 21, 2004


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